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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/086,059	02/27/2002	Jose Gutierrez-Rocca	540591-7095.1	1436
7590	07/14/2005			
Karen j. Messick kos pharmaceuticals 1001 brickell bay drive 25th floor miami, FL 33131			EXAMINER WILLIAMS, LEONARD M	
			ART UNIT	PAPER NUMBER
			1617	

DATE MAILED: 07/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/086,059

Applicant(s)

GUTIERREZ-ROCCA ET AL.

Examiner

Leonard M. Williams

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 April 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,9-11 and 13-16 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,9-11 and 13-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

Detailed Action

***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 04/18/2005 has been entered.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 4, 9-11, and 13-16 are rejected under 35 U.S.C. 102(e) as being anticipated by Corbo et al. (US Patent No. 6551617).

Corbo et al. teach, in col. 2 line 40 to col. 3 line 25, a coating composition comprising polyvinyl acetate, dimethylaminoethyl methacrylate, neutral methacrylic acid,

and a medicament. The polyvinyl acetate used in the formulation can be a blend such as KOLLIDON SR (a polyvinyl acetate/polyvinylpyrrolidone blend; ~8:2) and is present in the composition in ranges from 3-97% by weight. Corbo et al. teach, in col. 4 lines 55-65, that the compositions can contain ethyl cellulose as an additive and is present in amounts from 10-30% by weight. Corbo et al. teach, in col. 5 lines 15-40, that the coated medicament can be in the form of powders, tablets, liquid preparations, lozenges, wafers, chewing gums and that the medicament present can include acetaminophen, aspirin, ibuprofen, ranitidine, catopril etc.. anticipating the "...sustained/prolonged release pharmaceutical formulation...." of claim 1 and the "...formulation...wherein said water-soluble medicament is selected from..." of claims 4 and 10.

Corbo et al. teach, in col. 5 lines 37-56, that the coated medicament can be prepared by coating granules or crystals of a drug with the coating composition in a fluid bed chamber combining the coated granules or crystals with ingredients commonly used for making tablets, then compressing the mixture in tablet form anticipating the "...process for the preparation of the sustained/prolonged release pharmaceutical..." of claim 9 and the "...formulation...which comprises a modulated release pharmaceutical construct..." of claim 11, the "...process for preparing the sustained/prolonged release pharmaceutical formulation..." of claim 13, the "...process...wherein said tableting is conducted under direct pressure..." of claim 14, the "...process...wherein said polymer and drug are blended by means of wet granulation followed by dry blending..." of claim

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15, and the "...process....wherein all material are wetted prior to said blending and dried and milled after blending..." of claim 16.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Corbo et al. (US Patent No. 6551617).

Corbo et al. teach, in col. 4 lines 55-65, that the compositions can contain ethyl cellulose as an additive and that the ethyl cellulose is present in amounts from 10-30% by weight.

Corbo et al. does not teach the particular cellulose ethers of claim 3.

It would have been obvious to one of ordinary skill in the art at the time the invention was made that the commercially available cellulose ethers presented in claim

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3 could be used in the coating composition of Corbo et al. One would have been motivated to use any of the listed commercially available cellulose ethers as they are well known, have stable and defined, properties, and are commonly used in pharmaceutical formulations.

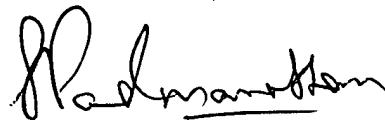
### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leonard M Williams whose telephone number is 571-272-0685. The examiner can normally be reached on MF 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

LMW

  
SREENI PADMANABHAN  
SUPERVISORY PATENT EXAMINER